U.S. FOOD & DRUG ADMINISTRATION

FDA and Industry GDUFA III Implementation Quarterly Meetings – 3Qtr 2024 Meeting
July 29, 2024, 2:00 PM – 3:00 PM
White Oak Campus and Virtual Zoom Meeting

Agenda

- Industry Topics
  - ❖ Missed GDUFA Goal Dates
  - ❖ CRL/IR Discrepancies

Participants

FDA Participant	Center	Industry Participant	Affiliation
Tiana Barnes	CDER	Rebecca Alcantara	BPTF (CuriaGlobal)
Carter Beach	CDER	David Gaugh	AAM
Ashley Boam	CDER	John Hekl	BPTF (AmbioPharm)
Kennerly Chapman	CDER	Kiran Krishnan	AAM (Apotex)
Rebecca Frey-Cooper	CDER	Brian McCormick	AAM (Teva)
Alonza Cruse	ORA	Giuseppe Randazzo	AAM
Kathleen Davies	CDER	Gil Roth	PBOA
Kristin Davis	CDER	Molly Ventrelli	AAM (Fresenius-Kabi)
Kim Dettelbach	OCC	Jennie Wang	BPTF (MilliPoreSigma)
Michael Kopcha	CDER	Brant Zell	BPTF (AmbioPharm)
Iilun Murphy	CDER	-	-
Susan Rosencrance	CDER	-	-

Industry Topics
Industry posed questions to FDA related to current implementation activities.

Missed GDUFA Goal Dates
Industry inquired about missed GDUFA goal dates and what actions can be taken to help better predict an action date for ANDAs past their goal dates, including to help companies prepare to launch products. The discussion focused on challenges and commitment to continue to look for potential opportunities to provide more clarity for these ANDAs.

CRL/IRL Discrepancies
Industry inquired about comments received in CRLs related to responses already submitted in IRs. FDA noted the need for specific examples from Industry to address this concern.